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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,312	03/01/2004	Joseph P. Reo	00757	9334

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WARNER-LAMBERT COMPANY
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EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,312	REO ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *47-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/30/2004 and 09/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Information Disclosure Statements dated 09/20/2004 and 07/30/2004 is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-46) in the reply filed on 8/2/07is acknowledged.

The traversal is on the ground(s) that searching the claimed subject matter in one application would not place a serious burden on the Examiner.

This was not found persuasive because the Examiner established serious burden by showing the different classification of the groups.

In addition, Applicants traverses the election of species requirement on the ground that it is improper since prosecution of the restricted subject matter in a single application would not place a serious burden on the Examiner.

This was not found persuasive because the search for the generic class of substances does not necessarily yield all the species listed in the claim. For example in Sparks et al. (US 5,354,556) reference, the sugar is disclosed, however, fructose will need a separate search.

Accordingly, the restriction requirement and election of specie requirement is still deemed proper and is therefore made FINAL.

Status of Claims:

3. Claims 47-67 are withdrawn.

4. Claims 1-46 are being presented for examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "polymer film coating at least 80% of the core of each of the particles", the recitation does not show 80% of the weight or the thickness or ..etc. An explanation is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8, 10-11, 15- 16, 20-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/763299 ('299 hereafter). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The two sets of claims recite a dry formulation of linezolid, instant claim recite at least one dose while '299 recite two or more, this encompass the number of doses in instant claims. It would have been obvious to one skilled in the art to modify the formulation parameters to increase or decrease the doses included. The instant claims and claims of '299 recite a polymer film and a viscosity enhancing material. The polymer in the two applications can be polymethacrylic acid copolymer and/or ethylcellulose and the viscosity enhancing substance is selected from a group of substances recited in instant claim 22 and claim 7 of '299. The surfactant in instant claim 10 is recited as the

plasticiser in claim 4 of '299. The taste masking substance (sucrose) of instant claims 15-16 is recited in claims 13-15, and 29-31 of '299. Instant claims also recite a particle size of (50-600 micron) which is recited in claim 21 of '299.

Instant claim 25 recites (which discloses that suspension is facilitated" in less than about three (3) minutes after addition of the aqueous solution to the dry formulation" (Page 15, claim 25)) includes the suspension time within 5 minutes of claim 19 of '299.

Given the formulation of microencapsulated linezolid, viscosity enhancing substances, and the resulting suspension after adding the dry formulation to an aqueous liquid such as water, the limitations of instant claims 20 and 34 regarding the homogeneous dispersion of air bubbles and solid particles would be obvious to one skilled in the art.

Since the instant application claims a dry formulation of coated drug particles and a viscosity enhancing substance, it is obvious over the claims of copending application '299 and thus, they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 16, 20-22, 27-29, 31-35, 41-42, and 46 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Percel et al. US 6451345 (Percel).

Percel teaches taste-masked coated particles (microcapsules) comprising linezolid (abstract). The microcapsules comprise sorbitol, and guar gum, microcrystalline cellulose which are recited in the instant claims as a viscosity enhancing substance (example 6), it may also comprise sucrose and lactose, which are mono- and disaccharides (col. 4, lines 20+). The particles are coacervated (abstract, col. 1, lines 46+, and claim 1). The coating is a methacrylic acid-methylmethacrylate copolymer or methacrylic acid-ethylacrylate copolymer (claim 8), or ethylcellulose (claims 5 and 8). The composition also includes sweeteners, and flavoring agents (claim 23). Instant claim 27 requires the microcapsules of linezolid suspended in an aqueous solution. Percel teaches that the contents of the Linezolid unit dose containers are suspended in an aqueous medium prior to oral administration to pediatric and geriatric patients (abstract) and the formulation may comprise sodium lauryl sulfate (a surfactant) see col. 4, lines 6+.

Giving the core comprising an oxazolidinone and polymer film coating that applicant recites in claims 1 and 27 the broadest reasonable interpretation, Percel's particles comprising linezolid which is coated with the same polymer will read on it though Percel does not disclose literally a core. Also the recitation of "non-diarrheogenic amount" in instant claim 1 does not limit the claim since the art knows where the non-diarrheogenic amount starts. Further, it is not the desire of any person skilled in the art to cause diarrhea to a patient as a side effect since it can be avoided.

Conclusion:

Claims 1-3, 5-9, 16, 20-22, 27-29, 31-35, 41-42, and 46 are anticipated by Percel.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percel et al. US 6451345 (Percel) in view of Sparks et al. US 5,354,556 (Sparks) and further in view of Tam et al. US 6495154 (Tam).

Percel has been discussed above. Percel also teaches that the coating materials account for approximately 30 to 60% of the composition by weight, though instant claim 4 recites at least 80% polymer film coating, it would have been obvious to one of ordinary skill in the art to adjust the coating percentage to achieve a specific release profile. The reference also teaches that the sugar content overlaps with range recited in instant claims 12 and 13 (see examples 5 and 6, table 1)

Percel did not disclose the particle size of 50 micron to 600 micron, and the percentages of ingredients recited in the instant claims.

Sparks teaches a controlled release powder containing microparticles, which can be readily formulated in liquid form (Col. 1, lines 44-46). The microparticles have an average particle size of from 0.1 to 125 micron (Col. 1, lines 59-60). The microparticles contain an active ingredient that may not be entirely coated by the non-toxic polymer (Col. 22, lines 10-21, claim 1). The powder can be "suspended in a liquid vehicle and will maintain its sustained release characteristics for a useful period of time. These dispersions or suspensions have both chemical stability and stability in terms of dissolution rate" (Col. 3, lines 21-25). Sparks also teaches polymers of acrylic and methacrylic acids (Col. 3, lines 35-36). The use of xanthan gum as a thickening agent to increase the viscosity is taught (Col. 6, lines 51-53). The oral suspensions using the polymer coated active ingredient masks the unpleasant taste (Col. 8, lines 24-26). Antibiotic suspensions are included in the preferred suspensions (Col. 8, lines 31-35). This reference also teaches "controlled release antibiotic formulations substantially free from the taste of the antibiotic for pharmaceutical or veterinary use" (Col. 1, lines 61-68).

Sugar is used as the taste-masking compound (Col. 22, lines 42- 44, claim 6). Water as a suitable liquid for the suspension is taught (Col. 6, lines 48-49). Sparks also teaches Particles prepared according to Example 1 were suspended in a sugar solution in water 66% (example 11), this amount reads on the amount recited in instant claim 12. Claim 13 requires an amount between 45-55%, however, adjusting the amount of a specific ingredient is within the skills of an artisan and depends on the need of the specific ingredient in the formulation. Also the ratio recited in claim 14 and percentages recited in claim 19 are obvious to people of ordinary skill in the art absent showing of unexpected results. Sparks also teaches an excipient used in association with the active ingredient will frequently have an active role to play following administration. For example, the excipient may be a surface-active agent which facilitates the transport of water into the particles (col. 7, lines 28+). Though instant claims requires the surfactant for the coating and not with the active agent, however, it is noted that a person of ordinary skill in the art would be motivated to include it in the coating to achieve the same purpose of facilitating the transport of water into the particles of the active agent inside the coating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the amounts of the ingredients disclosed by Percel because once a method of using a compound is known it is within the skill of a person of ordinary skill in the art to determine the optimum amounts to use and the optimum end points in using the compound and follow the particle size disclosed by Sparks

because Sparks teaches that the micro-particles invented can have a predetermined release of active ingredient (abstract).

Neither Percel nor Sparks teaches the use of fructose.

Tam provides a method wherein a pharmaceutical formulation is administered orally. The formulation comprises Taste-masking agents, i.e., flavorants, are used to disguise a bitter or undesirable taste of a component and/or impart a pleasant flavor to a pharmaceutical preparation. Particularly preferred taste-masking agents include sugars (e.g., glucose, sucrose, fructose and sorbitol). Accordingly, the art knew fructose as an equivalent to sucrose and sorbitol and it is not considered novel to use such sugar in the art. Note also that high fructose corn syrup is well known in the art as a taste masking product (col. 11, lines 42+).

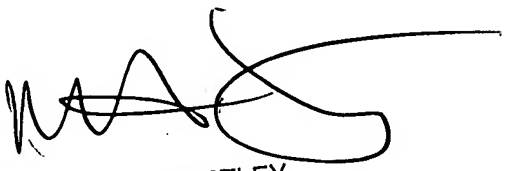
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use fructose as taste masking ingredient for the microparticles recited by Percel that has the particles size disclosed by Sparks which has an unacceptable taste because fructose is known in the art as an equivalent to other sugars that are used for the same reason. The expected result would be a dose or more of linezolid that is coated with a polymer and is taste masked.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
10/22/07



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER